

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES ONLY TO: WAVE 1 CASES ON PLAINTIFFS' EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OR, IN THE
ALTERNATIVE, TO LIMIT THE OPINIONS AND TESTIMONY STEPHEN M.
FACTOR, M.D.**

Dr. Factor is a pathologist with over 40 years of experience. His opinions are based on his vast expertise in the areas of pathology, wound healing, inflammation, and tissue integration. In their motion [Doc. 2015] and memorandum in support [Doc. 2020], Plaintiffs make no serious challenge to that expertise, or to Dr. Factor's methodology, but rather claim that because Dr. Factor's experience is not specific to mesh, then his testimony should be excluded. This is a flawed premise which this Court has repeatedly rejected. Moreover, Dr. Factor *does* have experience and expertise in mesh, and his experience in studying wounds generally also enables him to offer his opinions. Plaintiffs' motion to exclude or limit the testimony of Dr. Stephen M. Factor should be denied.

ARGUMENT

I. Dr. Factor is qualified to render his opinions, which are based on reliable methodology.

A. Dr. Factor's qualifications.

Dr. Factor readily admits that the bulk of his experience is not mesh-specific. Rather, he has over 40 years of experience in the area of clinical and anatomical pathology that has enabled him to offer the opinions he offers here. He is an anatomical pathologist, and currently serves as

Chairman of the Department of Pathology at Jacobi Medical Center and North Central Bronx Hospital, in New York City and is a tenured full professor of pathology at Albert Einstein College of Medicine. Factor Report at 1 [Doc. 2015-2, p. 3]. On a daily basis, he performs surgical pathology and cytopathology. *Id.* His department examines over 12,000 surgical pathology cases, 12,000 gynecologic and non-gynecologic cytopathology cases, and 40-50 autopsies yearly. *Id.*

Dr. Factor became board-certified in anatomic and clinical pathology in 1975, and the majority of his publications have been in the area of cardiovascular disease. *Id.* His studies have included such topics as wound healing; tissue injury; connective tissue in the heart, with a focus on structure-function relationships; the effects of collagen breakdown; tissue remodeling; and the effects of diabetes mellitus and systemic hypertension on tissue and blood vessels. *Id.* He has studied bio-prosthetic materials in animals and humans and mesh materials including polypropylene primarily for the repair of hernias. *Id.* at 1-2 [Doc. 2015-2, pp. 2-3]. In this litigation Dr. Factor has studied approximately 20 cases of gynecologic mesh. *Id.* at 3 [Doc. 2015-2, p. 3].

Plaintiff's argument is based upon the faulty premise that a pathologist must be a "mesh pathologist" to render an opinion regarding the body's reaction to mesh. This is simply false. Pathologists review tissue slides every day to determine the body's reaction to foreign bodies. And the process by which this assessment is made is the same—regardless of the composition of that particular foreign body. During the course of this MDL, this Court has repeatedly found pathologists to be qualified to provide testimony regarding their findings related to pathology, despite a lack of experience specific to mesh. *See, e.g., Frankum v. Bos. Sci. Corp.*, No. 2:12-CV-00904, 2015 WL 1976952, at *24 (S.D. W. Va. May 1, 2015) (anatomical and clinical

pathologist qualified to testify about pathology of mesh material despite lack of training in polymer science or testing of mesh products).

As Dr. Factor explains in his report, “[a]ll wounds of epidermis or mucosal-lined tissue (i.e. vagina, bladder, rectum, pelvic floor, etc.), regardless of whether they are surgical or accidental, heal with a relatively uniform pattern that is consistent from patient to patient. Healing is essentially similar between individuals, and between most mammalian species used in laboratory studies.” *Id.* Accordingly, his expertise in the area of wound healing need not be product-specific, but rather can be applied to any types of wounds.

With respect to Plaintiffs’ claim that Dr. Factor has exceeded the bounds of his expertise by offering opinions about the “design, biocompatibility, or physical properties” of the mesh, their challenge does not accurately depict Dr. Factor’s testimony. Plaintiffs have cited Dr. Factor’s testimony from a 2012 deposition in the *Pamela Wicker* and *Linda Gross* cases in New Jersey where Dr. Factor stated he would not be giving opinions about pore size, among other things. [Doc. 2020, p. 4]. But in the *Wicker* and *Gross* cases, Dr. Factor only offered case-specific opinions—he did not offer the general opinions now offered in the MDL Wave 1 cases. *See* Ex. A, *Gross* Report; Ex. B, *Wicker* Report; Ex. C, *Wicker* Supplemental Report.

Further, here, contrary to Plaintiffs’ suggestion, Dr. Factor does not seek to opine generally about mesh design or biomaterials. Rather, his opinions that touch on these subjects are derived from and linked to his experience and expertise within the field of pathology. In his report, Dr. Factor’s opinions concern (1) wound healing: acute and chronic inflammation; (2) acute versus chronic inflammatory cells; (3) tissue integration with mesh; (4) factors affecting wound healing with or without mesh; and (5) a general critique of Plaintiffs’ expert pathologist Dr. Iakovlev’s opinions. These are all areas within Dr. Factor’s expertise in the field of

pathology, both as they relate to wound healing and inflammation generally, but also as to his review of prosthetics, including mesh. In his experience as a surgical pathologist, Dr. Factor has studied hundreds of cases of vascular and valvular procedures with polypropylene and Prolene sutures, and has studied multinucleated giant cells and their association with foreign bodies by light microscopy and electron microscopy. Factor MDL General Report at 2 [Doc. 2015-2, p. 4]. Dr. Factor has studied mesh materials including polypropylene primarily in hernia repair, but has also studied approximately 20 cases of gynecologic mesh in his role as an expert witness. *Id.* He is amply qualified to offer his opinions about mesh generally, and Plaintiffs' motion should be denied.

Finally, to the extent that Dr. Factor's opinions touch on some physical properties of the mesh, "throughout these MDLs, [this Court has] allowed numerous pathologists to testify regarding the properties of polypropylene mesh." *Hall v. Boston Scientific Corp.*, No. 2:12-CV-08186, 2015 WL 868907, at *13 (S.D. W. Va. Feb. 27, 2015). As this Court has noted, a "a clinical pathologist 'will be knowledgeable in the areas of chemistry, hematology, microbiology, ... serology, immunology, and other special laboratory studies.'" *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *20 (S.D. W. Va. Sept. 29, 2014) (quoting 33 Am. Jur. Trials § 17 (1986)).

B. Dr. Factor's methodology.

Plaintiffs challenge Dr. Factor's methodology based on an excerpt from his deposition in the *Wicker* case where he testified he did not rely on materials in his reliance list, including writings from Drs. Klinge and Klosterhalfen. [Doc. 2020, p. 6]. This statement has no bearing on Dr. Factor's opinions in this case because of critical differences in *Wicker* and these cases.

As discussed above, in *Wicker*, Dr. Factor was offering case-specific testimony only and in the cited portion of the deposition was discussing his opinions about Ms. Wicker's mesh.

Thus, it is not surprising that the primary basis for his opinions was his review of the pathology specimens there in comparison to Ms. Wicker's. Here, by contrast, Dr. Factor offers general opinions.

In addition, Dr. Factor's reliance list in *Wicker* was far more extensive than his MDL General Report's reliance list. In *Wicker*, the reliance list included various depositions and medical records, company documents, and approximately 100 scientific publications. *See* Ex. B, Wicker Report, pp. 7-18. Here, Dr. Factor's reliance list is more tailored, consisting of 24 scientific publications cited in his Report, plus an additional 8 authorities not cited but relied on as background material. [Doc. 2015-2, pp. 25-26]. Thus, Plaintiffs' citation to Dr. Factor's testimony from *Wicker* where he said he did not rely on authorities on his reliance list is misleading at best.

In his Report, Dr. Factor has cited numerous reliable authorities in support of his opinions. *Id.* Plaintiffs make no challenge to Dr. Factor's reliance on any of these authorities for the propositions stated. Their motion should be denied.

II. Dr. Factor's opinions regarding anticipated inflammatory response are admissible.

Plaintiffs claim that Dr. Factor "does not know and is unable to offer any opinions concerning the expected inflammatory response to Ethicon's Prolene and Prolene Soft mesh devices." [Doc. 2020, p. 7]. This is incorrect and based on an out-of-context excerpt from testimony in a distinguishable case.

In the *Wicker* case, Dr. Factor stated he was not offering opinions about the expected inflammatory response of an average person to Prolift and could not quantify it without looking at large number of specimens. [Doc. 2020, p. 7]. However, as noted above, in the *Wicker* case Dr. Factor offered case-specific opinions only. And in his current expert report, which now does include opinions about inflammation not included in *Wicker*, Dr. Factor supports his statements

about the mild inflammatory response to the mesh with citations to reliable sources that do examine a large number of specimens.

For example, the Elmer study cited by Dr. Factor for his opinions regarding inflammatory response showed only a mild inflammatory response following implantation of the Prolift device in 10 women. *See* Ex. D, Elmer C, Blomgren B, Falconer C, et al.: Histological inflammatory response to transvaginal polypropylene mesh for pelvic reconstructive surgery. J Urol 2009; 181:1189-1195. In that study, the histological examinations were performed by a pathologist (like Dr. Factor) blinded to the outcome, and the study showed no statistically significant changes in macroscopic inflammatory grading assessment postoperatively. *Id.* at p. 3. These results were consistent with animal studies, such as the Hutchinson study relied on by Dr. Factor, which implanted 80 rats with different types of mesh. *See* Ex. E, Hutchinson R: An exploratory 91-day tissue reaction study of polypropylene-based surgical mesh in rats. (PSE ACC. No.00-0035) 2001. Twenty rats were implanted with Prolene Soft mesh and showed only a minimal to mild inflammatory reaction at all explanation time periods. *Id.* Similarly, the Falconer study cited by Dr. Factor examined 10 women who had been implanted with the Prolene material and observed only a minimal inflammatory reaction without a significant change in collagen solubility. Ex. F, Falconer C, Soderberg M, Blomgren B, et al.: Influence of different sling materials on connective tissue metabolism in stress urinary incontinent women. Int Urogynecol J 2001; Suppl 2:S19-S23.

Apart from the inapposite citation to the *Wicker* deposition Plaintiffs offer no challenge to Dr. Factor's qualifications to offer his opinion regarding inflammatory response and no challenge to his methodology. Dr. Factor is well-qualified to offer this opinion, which rests on reliable foundation. Plaintiffs' motion should be denied.

III. Dr. Factor is well-qualified to offer criticisms of Dr. Iakovlev's opinions

Dr. Factor provides specific criticisms of the methodology used and conclusions reached by Dr. Iakovlev as one pathologist criticizing the methodology and opinions of another pathologist. These criticisms are based on fundamental principles of pathology.

Plaintiffs make no particular challenge to any specific opinion of Dr. Factor's concerning Dr. Iakovlev. Rather, they rest on their previously stated criticisms of Dr. Factor. As explained, Plaintiffs' criticisms of Dr. Factor are without merit, and at most are matter for cross-examination, not exclusion. Their motion should be denied.

CONCLUSION

For these reasons, Plaintiffs' motion to exclude Dr. Stephen Factor [Doc. 2015] should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
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